UNITED STATES DISTRICT COURT EASTERN DISTRICT OF VIRGINIA NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

All End-Payor Class Actions

MDL No. 2836

No. 2:18-md-2836- RBS-DEM

REDACTED PUBLIC VERSION

MEMORANDUM OF LAW IN SUPPORT OF END-PAYOR PLAINTIFFS' MOTION FOR CLASS CERTIFICATION AND APPOINTMENT OF CLASS REPRESENTATIVES AND CLASS COUNSEL

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INTRODUCTION

The End-Payor Plaintiffs ("Plaintiffs") seek certification of a proposed class of third-party payors ("TPPs" or "Class") (defined below) pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure. TPPs are at the end of the pharmaceutical distribution chain (*i.e.*, End-Payors) and consist of entities, such as self-insured health and welfare plans or insurers, that indirectly purchase, pay and/or provide reimbursement for their members' prescription drug purchases. TPPs bring this case under state competition and unjust enrichment laws against Defendants Merck¹ and Glenmark² alleging that they entered into an unlawful anticompetitive agreement to settle a patent infringement litigation concerning ezetimibe, the key active pharmaceutical ingredient in Merck's branded cholesterol-control medication Zetia (the "Settlement Agreement").³

This is what the Federal Trade

Commission ("FTC") refers to as a "No Authorized Generic" or "No-AG" agreement.⁵ The FTC concluded that branded companies use "No-AG" deals to confer payments on first Abbreviated

¹ Defendant Merck includes the following entities: Merck & Company, Inc.; Merck Sharp & Dohme Corporation; Schering-Plough Corporation; Schering Corporation; and MSP Singapore Company LLC. *See* Plaintiffs' Consolidated Amended Complaint Class Action Complaint (ECF No. 130) ¶¶ 16-22.

² Defendant Glenmark includes the following entities: Glenmark Pharmaceuticals Ltd. and Glenmark Generics Inc., U.S.A. *Id.* ¶¶ 23-25.

³ Declaration of Michael M. Buchman dated November 18, 2019 ("Buchman Decl."), Ex. 1 (GLENMARK-ZETIA-00242734)

⁴ See CAC ¶¶ 1, 191; Buchman Decl., Ex. 2 (Declaration of Dr. Russell L. Lamb, Ph.D. ("Dr. Lamb Rprt.") ¶ 25; Buchman Ex. 3

⁵ Buchman Decl., Ex. 4 (FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (2011) ("FTC Report")) at 6.

New Drug Application ("ANDA") generic companies in exchange for generic companies' agreement to delay generic market entry.⁶ Notably, the FTC also concluded that the elimination of AG competition during the first generic ANDA filer's 180-day marketing exclusivity period under the Hatch-Waxman Act can be quantified – approximately 40% to 52% of the generic revenue during the 180-day period is captured by the AG.⁷ Applying these conclusions to this case, Plaintiffs' allege that Merck's "No-AG" agreement resulted in an approximately \$800 million payment to Glenmark.⁸ This type of large and unjustified payment can constitute an unlawful, anticompetitive "reverse payment" or "pay-for-delay" agreement in violation of the antitrust laws. See FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013); see also Buchman Decl., Ex. 4 (FTC Report) at iv.

Defendants' anticompetitive agreement: (i) enabled Merck to earn huge sums in additional Zetia monopoly revenues in the absence of generic competition; and (ii) provided assurance to Glenmark that it would receive an approximately \$800 million "payoff" in the form of additional generic Zetia revenue from Merck's no-AG promise.⁹ Pursuant to their *quid pro quo* deal,¹⁰ Glenmark delayed the launch of its generic Zetia until December 12, 2016, and Merck did not launch an AG of Zetia at any time during Glenmark's 180-day exclusivity period.¹¹

Id

⁶ *Id.* at iv (explaining that "[pay-for-delay] agreements involve a brand-name firm compensating a generic and the generic agreeing to delay its entry. One form that compensation can take is the brand's commitment, in exchange for the first-filer's agreement to delay entry, not to sell an AG during the first-filer's 180-day exclusivity period.").

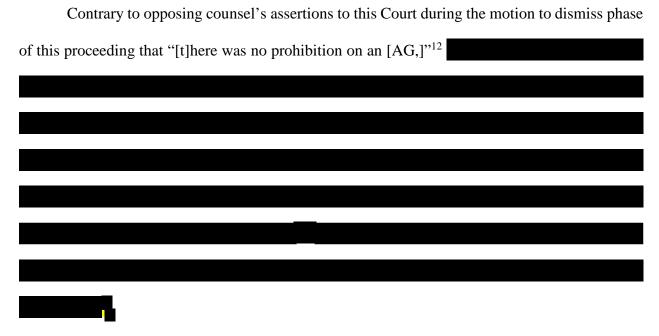
⁷ *Id.* at iii.

⁸ CAC ¶ 267.

⁹ CAC ¶¶ 267-68.

¹⁰ *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2019 WL 1397228, at *1, *8 (E.D. Va. Feb. 6, 2019), *adopted as modified*, 2019 WL 3761680 (E.D. Va. Aug. 9, 2019).

¹¹ CAC ¶¶ 254-256.



As a result of Defendants' unlawful agreement to delay generic competition, Plaintiffs and the Class, TPPs, paid over more for Zetia and generic Zetia than they otherwise would have in a fully competitive market.¹⁵

Federal courts routinely certify indirect purchaser/end-payor classes in pharmaceutical antitrust cases alleging the same type of anticompetitive conduct and harm as alleged here.¹⁶ In

Litigation Classes: *In re Loestrin 24 FE Antitrust Litig.*, No. 13-md-2472-WES-PAS, 2019 WL 5406077 (D.R.I. Oct. 17, 2019); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2019 WL 4735520 (E.D. Pa. Sept. 27, 2019); *Hosp. Auth, of Metro. Gov't of Nashville & Davidson Cty v. Momenta Pharm., Inc.*, No. 15-cv-01100, 2019 WL 4573433 (M.D. Tenn. Sept. 20, 2019); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*,

¹² Buchman Decl., Ex. 5 (Jan. 14, 2019 Hrg. Tr. at 33:19-21); *see also id.* at 22:9-12 (Court: "would you agree that this alleges an agreement that is the equivalent of a no AG agreement?" Glenmark counsel: "So, fortunately, I don't think I need to go that far because that isn't this case.").

¹³ Buchman Decl., Ex. 6 (GLENMARK-ZETIA-00435580-82)

¹⁴ *Id.*, Ex. 7 (MRKZETIA000874087) Ex. 8 (MRKZETIA000614647)

 $[\]overline{^{15}}$ *Id.* Ex. 2 (Lamb Report) ¶ 10; CAC ¶¶ 59-60; 64-69; 83-93.

¹⁶ See Buchman Decl., Ex. 9, listing:

this case, the requirements for certification under Rule 23 are similarly satisfied. *First*, the Class satisfies the requirements of Rule 23(a):

- the members of the Class are so numerous that joinder is impracticable;
- the claims of the class members involve common questions of law or fact;
- the claims of the named plaintiffs are typical of the claims of the other class members; and

No. 14-md-2503, 2017 WL 4621777 (D. Mass. Oct. 16, 2017); In re Lidoderm Antitrust Litig., No. 14-md-02521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017); In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168 (D. Mass. 2013), aff'd, 777 F.3d 9 (1st Cir. 2015); In re Flonase Antitrust Litig., 284 F.R.D. 207 (E.D. Pa. 2012); In re Wellbutrin XL Antitrust Litig., 282 F.R.D. 126 (E.D. Pa. 2011); In re Tricor Indirect Purchaser Litig., 252 F.R.D. 213 (D. Del. 2008); Ferrell v. Wyeth-Ayerst, Labs., Inc., No. 01-cv-447, 2007 U.S. Dist. LEXIS 44391, at *6 (S.D. Ohio June 19, 2007); In re Abbott Labs. Norvir Antitrust Litig., Nos. 04-cv-1511, 04-cv-4203, 2007 WL 1689899 (N.D. Cal. June 11, 2007); In re Children's Ibuprofen Oral Suspension Antitrust Litig., No. 04-mc-535 (D.D.C. Jan. 6, 2006) (ECF No. 30); In re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672 (S.D. Fla. 2004); Ferrell ν. Wyeth-Ayerst No. 01-cv-447 (S.D. Ohio July 1, 2004) (ECF No. 100); In re Cardizem CD Antitrust Litig., 200 F.R.D. 326 (E.D. Mich. 2001); In re Antibiotics Antitrust Actions, 333 F. Supp. 278, 280 (S.D.N.Y. 1971). See also In re Ampicillin Antitrust Litig., 55 F.R.D. 269 (D.D.C. 1972); In re Synthroid Mktg. Litig., 188 F.R.D. 287 (N.D. Ill. 1999) (third-party payor nationwide class for deceptive marketing); and In re Synthroid Mktg. Litig., 188 F.R.D. 295 (N.D. Ill. 1999) (consumer nationwide class).

Settlement Classes: In re Aggrenox Antitrust Litig., No. 14-MD-2516 (D. Ct. Mar. 6, 2018) (ECF No. 766); Ryan-House v. GlaxoSmithKline PLC, No. 02-cv-442, 2005 U.S. Dist. LEXIS 33711 (E.D. Va. Jan. 10, 2005); Buchman Decl., Ex. 22 (Ryan-House v. GlaxoSmithKline PLC, No. 02-cv-442 (E.D. Va. July 28, 2004) (ECF No. 137)); In re Tricor Indirect Purchaser Litig., No. 05-cv-360 (D. Del. May 8, 2009) (ECF No. 509); In re Abbott Labs. Norvir Antitrust Litig., No. 04-cv-1511 (N.D. Cal., Aug. 27, 2008) (ECF No. 612); Vista Healthplan, Inc. v. Warner Holdings Co. III, Ltd., 246 F.R.D. 349, 357 (D.D.C. 2007); In re Children's Ibuprofen Oral Suspension Antitrust Litig., No. 04-mc-535 (D.D.C. Dec. 11, 2006) (ECF No. 33); In re Remeron End Payor Antitrust Litig., Nos. 02-2007, 04-5126, 2005 U.S. Dist. LEXIS 27011 (D.N.J. Sep. 13, 2005); Nichols v. Smithkline Beecham Corp., No. 00-cv-6222, 2005 U.S. Dist. LEXIS 7061 (E.D. Pa. Apr. 22, 2005); In re Cardizem CD Antitrust Litig., 218 F.R.D. 508, 517 (E.D. Mich. 2003); In re Buspirone Antitrust Litig., No. 01-md-01413 (S.D.N.Y. April 21, 2003) (ECF No. 148); In re Warfarin Sodium Antitrust Litig., 212 F.R.D. 231, 264 (D. Del. 2002), aff'd, 391 F.3d 516 (3d Cir. 2004); In re Lorazepam & Clorazepate Antitrust Litig., 205 F.R.D. 369, 374, 396 (D.D.C. 2002); In re Terazosin Hydrochloride Antitrust Litig., No. 99-md-1317 (S.D. Fla. Dec. 19, 2002) (ECF No. 913).

- the named plaintiffs will fairly and adequately represent the interests of the Class. *Second*, the Class satisfies Fed. R. Civ. P. 23(b)(3):
- the parties opposing the Class have acted or refused to act on grounds generally applicable to the class;
- common questions of law and/or fact predominate over individual issues; and
- class certification is superior to other available means of adjudication.

Moreover, Class members can be readily identified by reference to objective criteria and in an administratively feasible manner. Plaintiffs' claims arise from a single anticompetitive scheme, which injured TPPs that purchased, paid and/or provided reimbursement for Zetia and its AB-rated generic equivalents, and are ideally suited for class treatment. Rule 23 was designed to facilitate the class-wide adjudication of similar claims and to achieve economies of time, effort and expense while promoting uniformity of decision as to all persons similarly situated. The class action mechanism is the superior method to adjudicate claims such as those alleged here. Accordingly, Plaintiffs respectfully request: (i) certification of the Class; (ii) designation of the named Plaintiffs as Class Representatives; (iii) appointment of Motley Rice LLC and Miller Law LLC as Co-Lead Class Counsel; and (iv) appointment of Furniss, Davis, Rashkind and Saunders, PC as Liaison Counsel.¹⁷

STATEMENT OF FACTS

For purposes of brevity, Plaintiffs will not repeat the facts alleged in the CAC as the Court is intimately familiar with them based on its extensive motion to dismiss decision. *In re Zetia* (*Ezetimibe*) *Antitrust Litig.*, No. 18-md-2836, 2019 WL 1397228, at *2-10 (E.D. Va. Feb. 6, 2019), *adopted as modified*, 2019 WL 3761680 (E.D. Va. Aug. 9, 2019). Plaintiffs also

¹⁷ By its Order dated August 25, 2018, this Court appointed the firms as Interim Co-Lead and Liaison Counsel and is familiar with their credentials. (ECF No. 105). For purposes of the Federal Rule of Civil Procedure 23(g) aspect of this motion, Interim Co-Lead and Liaison Counsels' firm resumes are attached as Exhibits 10, 11 and 12 to the Buchman Declaration.

incorporate by reference the facts set forth in Direct Purchaser Plaintiffs' memorandum of law in support of their motion for class certification.

ARGUMENT

I. THE IMPORTANCE OF CLASS CERTIFICATION

The antitrust laws are "as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms." *Comty. Commc'ns Co. v. City of Boulder*, 455 U.S. 40, 57 n.19 (1982) (quoting *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972)). Class actions are particularly important in the antitrust context since they are the most effective private enforcement mechanisms. *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 266 (1972); *In re Lorazepam & Clorazepate Antitrust Litig.*, 202 F.R.D. 12, 21 (D.D.C. 2001); *Shelter Realty Corp. v. Allied Maintenance Corp.*, 75 F.R.D. 34, 38 (S.D.N.Y.1977). Doubt in antitrust cases should, therefore, be resolved in favor of certifying the class. *In re Playmobil Antitrust Litig.*, 35 F. Supp. 2d 231, 239 (E.D.N.Y. 1998). Federal courts regularly certify End-Payors in cases, like this one, involving anticompetitive practices in the pharmaceutical industry. *See supra* n.16. For these reasons and those demonstrated below, the Class in this case should be certified.

A. General Standards for Applying Rule 23

Plaintiffs seeking certification under Rule 23(a) must establish four elements: (i) numerosity; (ii) commonality; (iii) typicality; and (iv) adequacy of representation. They must also establish one of the requirements of Rule 23(b). Pursuant to Local Civil Rule 7, Plaintiffs conducted a meet and confer with Defendants' counsel to request that they stipulate to the Rule 23(a) factors. It is Plaintiffs' understanding that Defendants do not presently intend to challenge numerosity under Rule 23(a)(1), but will not stipulate and intend to challenge the remaining Rule 23(a) factors. "A district court has broad discretion in deciding whether to certify a class." *Thorn*

v. Jefferson-Pilot Life Ins. Co., 445 F.3d 311, 317 (4th Cir. 2006) (citation omitted). While the analysis should be rigorous, "Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage." Amgen Inc. v. Conn. Retirement Plans and Trust Funds, 133 S. Ct. 1184, 1194-95 (2013). Courts may consider the merits of the proposed class's claims only where they are "relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." Brown v. Nucor Corp., 785 F.3d 895, 903 (4th Cir. 2015) (quoting Amgen, 133 S. Ct. at 1195).

B. Choice of Law

Plaintiffs' claims are brought under state law, and the Class encompasses purchases of Zetia and its AB-rated generic equivalents in 30 states, the District of Columbia, and Puerto Rico. In a multi-district litigation, courts typically apply the choice of law rules of each of the transferor courts, which in turn apply the choice of law rules of the states in which they sit. *In re Digitek Prod. Liab. Litig.*, No. 08-md-01968, 2010 WL 2102330, at *7 (S.D.W. Va. May 25, 2010); *In re Panacryl Sutures Prod. Liab. Cases*, 263 F.R.D. 312, 318 (E.D.N.C. 2009). The four transferor jurisdictions here – the Eastern District of New York, the Eastern District of Virginia, the District of Massachusetts, and the Central District of California (*see* ECF Nos. 1, 2) – look to the Restatement (Second) of Conflict of Laws for guidance and have adopted flexible approaches that require consideration of all of the relevant policies and interests.¹⁸ Because the underlying policy of an indirect purchaser action is consumer protection, "[t]he location of consumers' purchases . . . assumes special significance" in the choice of law analysis. *In re Relafen Antitrust Litig.*, 221

¹⁸ See, e.g. U.S. Bank Nat'l Ass'n v. Sun Life Assurance Co. of Canada, No. 14-cv-4703, 2016 WL 8116141, at *11 (E.D.N.Y. Aug. 30, 2016), adopted, 2017 WL 347449 (E.D.N.Y. Jan. 24, 2017); X-It Prods., LLC v. Walter Kidde Portable Equip., Inc., 227 F. Supp. 2d 494, 534 (E.D. Va. 2002); In re Relafen Antitrust Litig., 221 F.R.D. 260, 277-78 (D. Mass. 2004); Samica Enters., LLC v. Mail Boxes Etc. USA, Inc., 637 F. Supp. 2d 712, 728 (C.D. Cal. 2008).

F.R.D. 260, 277-78 (D. Mass. 2004). Thus, the Class' purchases of the drugs at issue in this case are governed by the law of the state in which the purchases were made. *See In re Flonase Antitrust Litig.*, 815 F. Supp. 2d 867, 880-85 (E.D. Pa. 2011) (applying the laws of the states where Flonase purchases were made after performing a detailed choice of law analysis).¹⁹

II. THE PROPOSED CLASS

The Class is defined as:

All Third-Party Payor entities that, for consumption by their members, employees, insureds, participants, or beneficiaries, and not for resale, indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Zetia or its AB-rated generic equivalents in any form, that was sold through a retail pharmacy, including mail-order pharmacies and long-term care pharmacies, in Alabama, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia West Virginia and Wisconsin from July 1, 2012²⁰ through November 18, 2019.

The following entities are excluded from the Class:

- a. Defendants and their subsidiaries and affiliates;
- b. All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;
- c. All entities who purchased Zetia or generic Zetia for purposes of resale or directly from Defendants or their affiliates;
- d. Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members); and
- e. Pharmacy benefit managers.

¹⁹ See also Wellbutrin XL, 282 F.R.D. at 135-36 ("The place of purchase is where the relationship between the parties is centered; it is where the transaction with the alleged overcharge actually occurs" as opposed to the "chance location of the TPP's principal place of business, the location of the TPP's [pharmacy benefit manager], or an individual purchaser's residence.").

²⁰ The CAC alleges that the Class Period began on December 6, 2011. CAC ¶ 311. Plaintiffs have revised that date to July 1, 2012.

For the reasons set forth below, the Class satisfies the requirements of Rule 23 and should be certified.

III. CLASS CERTIFICATION IS APPROPRIATE UNDER FED. R. CIV. P. 23(a)

A. Class Members Are So Numerous That Joinder Is Impracticable

Rule 23(a)(1) requires that members of a class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "The Fourth Circuit has held that '[n]o specified number is needed to maintain a class action." Report & Recommendation at 4, *In re Zetia (Ezetimibe) Antitrust Litig.*, (Oct. 1, 2019) (ECF No. 668), *adopted*, 2019 WL 5712472, at *1 (E.D. Va. Nov. 5, 2019) (hereinafter "*Zetia* R&R") (quoting *Brady v. Thurston Motor Lines*, 726 F.2d 136, 145 (4th Cir. 1984). While there is no mechanical test for numerosity, classes of forty or more generally satisfy the numerosity requirement. *Id.* (citing *In re Titanium Dioxide Antitrust Litig.*, 284 F.R.D. 328, 337 (D. Md. 2012).²¹

Here, Class members purchased, paid, and/or provided reimbursement for

See Buchman Decl., Ex. 2, Declaration of Russell L. Lamb, Ph.D.

("Dr. Lamb Rprt.") at 13 n.54. Moreover, in 2016 alone, there were over 27,000 employer-sponsored health plans in the United States that were not fully insured. Buchman Decl. Ex. 13

(Declaration of Laura R. Craft) ("Craft Decl.") ¶ 11. Given the number of prescriptions for Zetia and generic Zetia, common sense dictates that the number of Class members far exceeds forty

TPPs. See Playmobil, 35 F. Supp. 2d at 239 (citing 4 Herbert B. Newberg, Newberg on Class Actions § 18.03 n.17 (2d ed.1985)) ("numerosity may be supported by common sense assumptions, and it is especially appropriate in antitrust actions brought under Rule 23(b)(3)."); In re Loestrin

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²¹ See also Hutson v. CAH Acquisition Co. 10, LLC, No. 15-cv-742, 2016 WL 4289473, at *2 (M.D.N.C. Aug. 15, 2016) (quoting 1 William B. Rubenstein, Newberg on Class Actions § 3:12 (5th ed. 2012)).

24 FE Antitrust Litig., No. 13-md-2472, 2019 WL 5406077, at *27 (D.R.I. Oct. 17, 2019) (numerosity of TPP class established where the number of U.S. employer-sponsored health plans exceeded 24,000 during the class period). Accordingly, Plaintiffs have readily satisfied Rule 23(a)(1).

B. Plaintiffs' Claims Present Common Issues of Law or Fact

Rule 23(a)(2) requires "questions of law or fact common to the class" and sets a "low bar." Fed. R. Civ. P. 23(a)(2); *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 19 (1st Cir. 2008). A common question is one that is "capable of class-wide resolution – which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011); *see also Knight v. Lavine*, No. 12-cv-611, 2013 WL 427880, at *3 (E.D. Va. Feb. 4, 2013). The Rule does not require that *all* questions be common to the class. To the contrary, even a single common question will suffice. *Wal-Mart*, 564 U.S. at 359. "[I]n the antitrust context, courts have generally held that an alleged conspiracy or monopoly is a common issue that will satisfy Rule 23(a)(2)." *Zetia* R&R at 5 (citing *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 300 (D.D.C. 2007)); *Am. Sales Co., LLC v. Pfizer, Inc.*, No. 14-cv-361, 2017 WL 3669604, at *11 (E.D. Va. July 28, 2017), *adopted*, 2017 WL 3669097 (E.D. Va. Aug. 24, 2017) ("*Celebrex*") (same).²²

²² See also Brown v. Cameron-Brown Co., 92 F.R.D. 32, 38 (E.D. Va. 1981) ("an allegation of conspiracy or monopolization will generally be treated as a 'central' or 'single overriding' issue . . . sufficient to establish a common question."); *Hosp. Auth.*, 2019 WL 4573433, at *7 (recognizing that "[i]n antitrust cases, the commonality requirement is often easily met" and certifying End-Payor class); *Titanium Dioxide*, 284 F.R.D. at 337.

Here, many key questions of law or fact are common to the Class, the most important of which center on Defendants' anticompetitive conduct. As detailed in the CAC, key questions of law or fact that are common to the Class include:

- a. Whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;
- b. To the extent procompetitive justifications exist, whether there were less restrictive means of achieving them;
- c. Whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market;
- d. Whether Defendants' scheme, in whole or in part, has substantially affected intrastate and/or interstate commerce;
- e. Whether Defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiffs and the members of the Class;
- f. Whether Merck and Glenmark conspired to delay generic competition for Zetia;
- g. Whether, pursuant to the reverse payment agreement, Merck's promise not to compete against Glenmark's generic product constituted a payment;
- h. Whether Merck's agreement with Glenmark was necessary to yield some cognizable, non-pretextual procompetitive benefit;
- i. Whether Merck's compensation to Glenmark was large and unexplained;
- j. Whether the reverse payment agreement created a bottleneck to further delay generic competition for Glenmark;
- k. Whether the reverse payment harmed competition;
- 1. Whether, before December 12, 2016, Merck possessed the ability to control prices and/or exclude competition for Zetia;
- m. Whether, from December 12, 2016, Merck and Glenmark possessed the ability to control prices and/or exclude competition for Zetia;
- n. Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Zetia;

- o. Determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic conduct caused; and
- p. The quantum of overcharges paid by the Class in the aggregate.

See CAC at ¶ 317. As in similar cases, each of these common questions can be resolved with class-wide evidence. Thus, the Class satisfies Rule 23(a)(2).

C. Plaintiffs' Claims Are Typical of Those of the Class

Rule 23(a)(3) is satisfied if "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). The claims of named plaintiffs are typical of the class when the plaintiffs "possess the same interest[s] and suffer the same injury as the class members." *Broussard v. Meineke Disc. Muffler Shops, Inc.*, 155 F.3d 331, 338 (4th Cir. 1998). Typicality can be shown if the named plaintiffs' "claims arise from the same events and are premised on the same legal theories as the claims of the class members" and factual variances, such as the amount of damages claimed, do not prohibit a finding of typicality. *Jeffreys v. Commc'ns Workers of Am., AFL-CIO*, 212 F.R.D. 320, 322 (E.D. Va. 2003). The typicality requirement is "liberally construed by courts." *Celebrex*, 2017 WL 3669604, at *11. "[I]n the

²³ See Loestrin, 2019 WL 5406077, at *27 (commonality satisfied where the anticompetitive conduct alleged by End-Payors involved numerous common questions of law and fact); Solodyn, 2017 WL 4621777, at *12, n.12 (commonality established where "EPPs' claims all stem from the same alleged anticompetitive conduct"); Hosp. Auth., 2019 WL 4573433, at *7 (commonality satisfied where End-Payors' claims were based on defendants' anticompetitive conduct); Relafen, 221 F.R.D. at 267 (commonality established because all class members' claims alleged injury arising from same conduct by defendants); In re Lidoderm Antitrust Litig., No. 14-md-02521, 2017 WL 679367, at *1 (N.D. Cal. Feb. 21, 2017) (common questions included: "Did defendants engage in anticompetitive conduct? Did that conduct lead to overcharges for brand and generic lidocaine patches? What aggregate damages resulted from the overcharges?"); In re Flonase Antitrust Litig., 284 F.R.D. 207, 217 (E.D. Pa. 2012) (commonality established because "proof of the essential elements" of antitrust claims would focus on "allegations surrounding [defendant's] alleged conduct in delaying generic entry").

²⁴ See also In re Evergreen Ultra Short Opportunities Fund Secs. Litig., 275 F.R.D. 382, 389 (D. Mass. 2011); accord In re Warfarin Sodium Antitrust Litig., 212 F.R.D. 231, 250 (D. Del. 2002), aff'd, 391 F.3d 516 (3d Cir. 2004); In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 304 (E.D. Mich. 2001); Synthroid, 188 F.R.D. at 299.

antitrust context, typicality 'will be established by plaintiffs and all class members alleging the same antitrust violations by defendants'" or where all claims arise from some overarching scheme of the defendants. *Id.*²⁵

Here, named Plaintiffs' and the Class' claims arise from the same course of conduct, namely, Defendants' anticompetitive scheme to delay the availability of generic Zetia. Defendants suppressed competition in a way that caused the named Plaintiffs and the Class to suffer the same injury – paying *supra*-competitive prices for Zetia and its AB-rated generic equivalent. The claims are based upon common legal theories: conspiracy in restraint of trade and monopolization. The fact that the claims arise under multiple state laws does not defeat typicality where, as here, the relevant state laws²⁶ mirror federal law and each other in their essential elements. *See Flonase*, 284 F.R.D at 217-18 (End-Payor's state law claims typical because the "state law claims for monopolization, [unfair and deceptive trade practices], and unjust enrichment arise from an identical course of conduct" by the defendant).²⁷ Accordingly, the typicality requirement is easily satisfied.

²⁵ See also Suboxone, 2019 WL 4735520, at *22 (typicality established where "the claims of the named Plaintiffs and the absent class members rely on the same legal theories and arise from the same 'core pattern' of alleged conduct by the Defendants"); Hosp. Auth., 2019 WL 4573433, at *8 (typicality satisfied where "Plaintiffs and putative [End-Payor] class members have claims that arise from the same course of conduct—the Defendants' alleged anticompetitive conspiracy to reduce generic competition in the enoxaparin market and reap the benefits of the resulting overcharges."); In re Vitamins Antitrust Litig., 209 F.R.D. 251, 260 (D.D.C. 2002) ("[T]his theory of an overarching conspiracy to fix prices and allocate the market in violation of antitrust laws will be common to all class members"); Carbon Black, 2005 WL 102966, at *12; In re Prudential Ins. Co. of Am. Sales Practice Litig., 148 F.3d 283, 310 (3d Cir. 1998); In re NASDAQ Market-Makers Antitrust Litig., 169 F.R.D. 493, 511 (S.D.N.Y. 1996); In re Sumitomo Copper Litig., 194 F.R.D. 480, 482 (S.D.N.Y. 2000).

²⁶ Plaintiffs have compiled the applicable state and federal antitrust and consumer protection statutes and the cases describing their similarities in Exhibit 14 to the Buchman Declaration.

²⁷ See also In re Terazosin Hydrochloride, 220 F.R.D. 672, 687 (S.D. Fla. 2004) ("[T]he claims of the consumer and the third-party payer class representatives are not only typical of the claims of all class members, they are virtually identical in nature, notwithstanding variations in the amount

D. Plaintiffs Will Adequately Represent the Class

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "The adequacy inquiry . . . serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 625 (1997). "For a conflict of interest to prevent plaintiffs from meeting the requirement of Rule 23(a), that conflict 'must be fundamental. It must go to the heart of the litigation." *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 430-31 (4th Cir. 2003) (quoting 6 Alba Conte & Herbert B. Newberg, *Newberg on Class Actions* § 18:14 (4th ed. 2002)).

Where, as here, the overarching question of the claims are based on the defendants' conduct, named Plaintiffs and the Class have the same objective: proving that Defendants acted unlawfully and that they paid overcharges as a result. There is no conflict because this common purpose occupies the "heart of the litigation." *Id.; see also Celebrex*, 2017 WL 3669604, at *12 ("The relevant issue on class certification is whether the named members of the class and the absent class members suffered the same type of overcharge as a result of [defendant's] conduct[.]").

Moreover, Plaintiffs have retained experienced counsel who have previously prosecuted claims similar to those in this case, and who have vigorously litigated this case and will continue to do so. *See Suboxone*, 2019 WL 4735520, at *38 (finding that class counsel, including Miller Law LLC and Motley Rice LLC, "have significant experience litigating complex class actions . . .

of damages. Consequently, if one class representative is able to prove that Defendants' alleged anticompetitive acts caused an overcharge for terazosin hydrochloride, or that Defendants were unjustly enriched at Indirect Purchaser Plaintiffs' expense, such proof will likewise prove the case on liability for every other class member.").

. [and] over the lengthy course of this litigation, counsel have vigorously represented the proposed class's interests."). Rule 23(a)(4) is, therefore, also satisfied.

E. The Class Is Ascertainable

Along with four explicit requirements under Rule 23(a), some courts have also recognized an "implicit threshold requirement that the members of a proposed class be 'readily identifiable." *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014) (quoting *Hammond v. Powell*, 462 F.2d 1053, 1055 (4th Cir. 1972)). This principle is sometimes referred to as "ascertainability." *Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 655 (4th Cir. 2019). A class is ascertainable if "a court can readily identify the class members in reference to objective criteria." *Id.* (quoting *EQT Prod. Co.*, 764 F.3d at 358). The goal of this principle "is not to 'identify every class member at the time of certification,' [] but to define a class in such a way as to ensure that there will be some 'administratively feasible [way] for the court to determine whether a particular individual is a member' at some point." *Id.* at 658 (quoting *EQT* 764 F.3d 347 at 358; 7A Charles Alan Wright et al., *Federal Practice and Procedure* § 1760 (3d ed. 2005)).²⁸

There are readily available, detailed data sources routinely used in the data-rich pharmaceutical industry. Using the one or more of the layers of purchase data available from pharmacy benefit managers ("PBMs") and pharmacies, Plaintiffs can reliably identify Class members by reference to the objective criteria in the class definition: (i) TPP purchases of Zetia and/or their generic equivalents, not for resale; (ii) in applicable states; (iii) during a discrete time period.²⁹ Excluded from the Class are categories of purchasers who did not pay overcharges (*e.g.*,

²⁸ See also Suboxone, 2019 WL 4735520, at *41-42 (rejecting defendant's unsupported argument that a list of class members was required to establish ascertainability and stating that "EPPs need not identify the class members at this juncture of the litigation").

²⁹ Loestrin, 2019 WL 5406077, at *28 (finding similarly defined TPP class ascertainable); *Solodyn*, 2017 WL 4621777, at *13-14 (finding End-Payor class ascertainable); *Nexium*, 777 F.3d at 19 ("The class definition here satisfies [the ascertainability] standards by being defined in terms of

fully-insured health plans) and others, which are also defined by reference to objective criteria. CAC at \P 312.

Plaintiffs' expert, Laura R. Craft of OnPoint Analytics, Inc. explains how detailed, transaction-level pharmaceutical industry data exists to identify Class members:

One of the defining characteristics of the U.S. pharmaceutical industry is the completeness, redundancy, and detail of its contemporaneously generated transaction data. There is perhaps no other consumer good where so much information is recorded by so many different participants in connection with an individual sales transaction. It is this robust data that makes it possible to identify Class members, apply exclusions, and assure that remaining members have in fact been injured.

Craft Decl. ¶ 14 (emphasis added); *see also id.* ¶ 5-6. Other federal courts have recently recognized that the pharmaceutical industry is replete with layers of purchase data, which can be collected from every transactional level and used to identify TPPs who purchased, paid and/or provided reimbursement for Zetia or generic Zetia.³⁰

Ms. Craft explains that all or nearly all of the industry data necessary to identify Class membership is conveniently concentrated among a handful of PBMs, who maintain detailed purchase data on prescription drug claims, including payment amounts, coverage and plan characteristics. *Id.* ¶¶ 17-21. The top PBMs confirm that they maintain this readily accessible data in an industry standard format that can identify every TPP that has purchased a drug.³¹

purchasers of Nexium during the class period (with some exceptions that also satisfy objective standards)."); *Lidoderm*, 2017 WL 679367, at *29 n.41 (finding that end-payor plaintiffs' expert's opinion that pharmacy and PBM records existed and were available supported ascertainability).

³⁰ Loestrin, 2019 WL 5406077, at *28 (certifying a TPP class under a heightened ascertainability requirement and finding that Plaintiffs, through their pharmaceutical industry experts, including Ms. Craft, demonstrated that requisite data sufficient to identify TPP class members and excluded entities could be obtained, compiled and analyzed); *Solodyn*, 2017 WL 4621777, at *13-14.

³¹ See also Buchman Decl. Ex. 15 (Express Scripts, Inc. Declaration) ¶ 5; Ex. 16 (Schaper (Caremark) Declaration) ¶ 6; Ex. 17 (Lahman (OptumRx) Declaration) ¶ 5; Ex. 18 (Express Scripts, Inc. Declaration) ¶¶ 6-8; Ex. 19 (OptumRx, Inc. Declaration) ¶¶ 7-10; Ex. 20 (Prime Therapeutics LLC Declaration) ¶¶ 9-12.

Moreover, the electronic data is maintained in electronic format using standardized fields. Craft Decl. ¶¶ 24-28. Electronic PBM data has been used in other cases to identify class members and can easily be merged, standardized and reviewed to identify Class members and details of their Zetia and generic Zetia purchases in this case. *Id.* ¶ 6.³² Ms. Craft, a pharmaceutical data analysis expert who has done this work before, explains that "[t]his process is manageable and can be carried out programmatically[.]" *Id.* ¶ 6. Moreover, Plaintiffs can also readily identify exclusions from the Class. *Id.* ¶ 29. As Ms. Craft explains:

- Defendants and their subsidiaries and affiliates, to the extent they operate a TPP, can be identified by Defendants. *Id.* ¶ 30.
- Entities that purchase directly from Defendants are identifiable from Defendants' own sales records. *Id*.
- Government entities are readily identifiable in PBM data. *Id.* ¶ 31.
- Fully-insured health plans are readily identifiable through PBM data. *Id.* ¶ 33. If necessary, this data can be cross-checked against publicly available information regarding self-insured employee benefit plans. *Id.* ¶ 34.
- PBMs are easily identifiable given that their identities are well known. *Id.* ¶ 35. Because PBMs are not End-Payors, do not pay for the prescription drug purchases of their clients, and merely act as their clients' service providers, no data analysis or further action is required to "exclude" PBMs from the Class data. *Id.* ¶¶ 35-38.³³

Other federal courts analyzing similar End-Payor classes have found an ascertainability requirement satisfied through methods similar to the method proposed by Plaintiffs and Ms. Craft.³⁴ Moreover, at least one court in this district found that ascertainability was satisfied where

³² See, e.g., In re Relafen Antitrust Litig., 231 F.R.D. 52, 64 (D. Mass. 2005).

³³ See also Buchman Decl. Ex. 18 (Express Scripts, Inc. Declaration) ¶ 9; Ex. 19 (OptumRx, Inc. Declaration) ¶¶ 4-6; Ex. 20 (Prime Therapeutics LLC Declaration) ¶¶ 7-8.

³⁴ Loestrin, 2019 WL 5406077, at *29 ("Prescription drug transactions are well documented and TPPs have the capability to retrieve information about the drugs they have purchased, the date on which they were purchased, and the price paid for the drugs. These records are maintained by some combination of the TPPs, the PBMs, and pharmacies. Most TPPs retain PBMs to administer prescription drug benefits to their members and members' beneficiaries, and PBMs process claims related to pharmaceutical purchases at pharmacies (i.e., at the point of sale).") (internal citations

plaintiffs proposed "dataset searches and other forms of electronic data analysis" followed by "additional manual review" to ascertain class members. *Soutter v. Equifax Info. Servs., LLC*, 307 F.R.D. 183, 197 (E.D. Va. 2015) (Payne, J.). Thus, based upon the layers of purchase information in this data-rich industry and the methods available to use the information to identify Class members, Plaintiffs have established that the Class is ascertainable as they have previously done in other cases.

IV. CLASS CERTIFICATION IS APPROPRIATE UNDER FED. R. CIV. P. 23(b)(3)

Class certification is appropriate under Rule 23(b)(3) if "questions of law or fact common to class members predominate over any questions affecting only individual members" and if "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Both requirements are met here.

A. Common Issues Predominate Across Plaintiffs' Antitrust Claims

The predominance inquiry "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem*, 521 U.S. at 623. To establish predominance, plaintiffs must show that "elements of their claim can be proven by evidence common to the members of their class." *Zetia* R&R at 7 (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311-12 (3d Cir. 2008)). "Plaintiffs are not required 'to prove that each elemen[t] of [their] claim [is] susceptible to classwide proof,' but only that 'common questions predominate over any questions affecting only individual [class] members." *Id.* (quoting *Amgen*, 568 U.S. 455, 469 (2013). Thus, where one or more common questions predominate regarding liability, individual issues regarding damages do not stand in the way of class certification. *Celebrex*, 2017 WL 3669604, at *16. The issues at the heart of this litigation—Plaintiffs' theories of liability, market

omitted); *Suboxone*, 2019 WL 4735520, at *41-43; *Solodyn*, 2017 WL 4621777, at *13-14; *Lidoderm*, 2017 WL 679367, at *29 n.41.

power, antitrust impact and aggregate damages—are common to the Class. Plaintiffs, therefore, meet their burden of establishing predominance.

1. Common Issues Predominate as to Theories of Liability

"In antitrust actions, '[p]redominance is a test readily met" where, as here, plaintiffs' theories of liability are necessarily premised on the defendants' conduct, not on issues particular to individual class members. *Solodyn*, 2017 WL 4621777, at *6 (quoting *Amchem*, 521 U.S. at 625); *see also Celebrex*, 2017 WL 3669604, at *13. All of Plaintiffs' theories of liability in this case, as in similar pay-for-delay cases, focus squarely on Defendants' unlawful conduct. The key question is whether the brand manufacturer (Merck) engaged in anticompetitive conduct by paying a potential generic competitor (Glenmark) to delay market entry of a competing generic product. Plaintiffs' common proof relating to their pay-for-delay allegations will include: (i) analysis of the terms of the relevant agreement;

³⁵ See, e.g., Hosp. Auth., 2019 WL 4573433, at *11 (common issues as to defendants' conduct predominated); Lidoderm, 2017 WL 679367, at *1 (same); Flonase, 284 F.R.D. at 218 (liability "can be proven through class-wide, common evidence because these issues focus on [defendant's] conduct, not on the actions of the individual class members."); Relafen, 221 F.R.D. at 275 ("The alleged antitrust violation relates solely to [defendant's] conduct, and as such, constitutes a common issue subject to common proof."); Teva Pharm. USA, Inc. v. Abbott Labs., 252 F.R.D. 213, 228 (D. Del. 2008) (common issues predominated because "each putative class member, had they pursued their claims individually, would have been required to prove identical facts, such as defendants'... exclusionary scheme... conspiracy, and unreasonable restraint of trade."); In re Neurontin Antitrust Litig., No. 02-cv-1390, 2011 WL 286118, at *6 (D.N.J. Jan. 25, 2011) ("Courts have routinely found that proof of this [antitrust] violation focuses on the defendant's conduct, not on the conduct of individual class members, and is therefore well suited for class treatment."); Natchitoches Par. Hosp. Serv. Dist. v. Tyco Int'l, Ltd., 247 F.R.D. 253, 269-70 (D. Mass. 2008) (in antitrust cases, classwide liability issues such as conspiracy or monopolization can predominate over individual issues); In re Scrap Metal Antitrust Litig., 527 F.3d 517, 535 (6th Cir. 2008) (in antitrust cases, "proof of the *conspiracy* is a common question that is thought to predominate over the other issues of the case."); McDonough v. Toys 'R Us, Inc., 638 F. Supp. 2d 461, 479-482 (E.D. Pa. 2009) (predominance satisfied where proof will focus on defendant's conduct).

³⁶ See Actavis, 133 S. Ct. at 2236. See also In re Aggrenox Antitrust Litig., No. 14–md–2516, 2015 WL 4459607, at *10 (D. Conn. July 21, 2005) (in an Actavis case, "what matters is whether a settlement postpones market entry").

These common issues are enough to establish predominance. *See* Buchman Decl., Ex. 22 (*Ryan-House v. GlaxoSmithKline PLC*, No. 02-cv-442 (E.D. Va. July 28, 2004) (Morgan Jr., J.) (ECF No. 137) at 3 (a pay-for-delay allegation "raises issues that predominate over any individual questions")); *see also Flonase*, 284 F.R.D. at 219-20 (finding that common issues of fact and law predominate on liability); *Lidoderm*, 2017 WL 679367, at *1.

The fact that Plaintiffs' claims are brought under state antitrust, consumer protection and unjust enrichment laws does not alter this conclusion. In similar pay-for-delay cases, federal courts "have certified classes in antitrust actions like this one despite the need to apply numerous states' laws." *Solodyn*, 2017 WL 4621777, at *19 (certifying class where End-Payors asserted fifty distinct claims under the laws of forty different jurisdictions) (citing *In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168, 176 (D. Mass. 2013), *aff'd*, 777 F.3d 9 (1st Cir. 2015) (twenty-six state laws at issue).³⁷ As one federal court recently found, "differences in the state [antitrust, consumer protection and unjust enrichment] statutes that Plaintiffs assert claims under . . . are not material [T]he fundamental issues under these statutes remains the same – proving that

³⁷ See also Relafen, 221 F.R.D. at 278-94 (twelve states' antitrust laws at issue); Lidoderm, 2017 WL 679367, at *27 (seventeen states' laws at issue)); Loestrin, 2019 WL 5406077 (certifying TPP class under the laws of 29 states); Suboxone, 2019 WL 4735520, at *44 (certifying End-Payor class and finding that "even though various state laws are used for the EPP issues class, these issues will utilize the same operative evidence to establish liability."); Flonase, 284 F.R.D. at 219 (predominance satisfied where plaintiffs would "utilize the same operative evidence" to prove defendants' liability for state antitrust, consumer protection and unjust enrichment claims); Warfarin 391 F.3d at 528 (antitrust and consumer protection allegations "naturally raise several questions of law and fact common to the entire class and which predominate over any issues related to individual class members").

putative plaintiffs were forced to pay a higher price in the absence of generic [] competition." *Hosp. Auth, of Metro. Gov't of Nashville & Davidson Cty v. Momenta Pharm., Inc.*, No. 15-cv-01100, 2019 WL 4573433, at *18 (M.D. Tenn. Sept. 20, 2019); *see also Lidoderm*, 2017 WL 679367, at *27 (differences among state laws claims not "material or even significant").

Here, each of the applicable state antitrust statutes mirrors the federal antitrust laws, contains a federal harmonization provision, and/or has been interpreted in harmony with federal law. Buchman Decl., Ex. 14 (compiling applicable federal and state laws and decisions); *see also Zetia*, 2019 WL 1397228 at *22 (concluding that Plaintiffs' state antitrust law claims are based on the same set of allegations that are sufficient to state claims under Sections 1 and 2 of the Sherman Act). The consumer protection statutes, modeled from Section 5 of the FTC Act, 15 U. S. C. § 45(a)(1), have been interpreted to permit recovery for anticompetitive, unfair or unconscionable conduct, and Plaintiffs' claims under these statutes are premised on the same unlawful conduct as their antitrust claims. *See* CAC ¶¶ 350-359; *see also FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948) ("all conduct violative of the Sherman Act may likewise come within the unfair trade practice prohibitions of the [Federal] Trade Commission Act"). Further, Plaintiffs' unjust enrichment claims are premised on the same alleged facts and will be proven using the same evidence as their antitrust and consumer protection claims. *See* CAC ¶¶ 361-373.

2. Common Issues Predominate as to Market Power

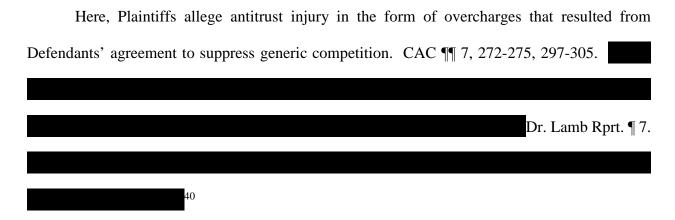
Market power can be established directly (through proof of supracompetitive pricing) or indirectly (through proof that defendants have a dominant share in the relevant market).³⁸ Here, Plaintiffs will prove market power through evidence that is common to the Class, including

³⁸ See R. J. Reynolds Tobacco Co. v. Philip Morris Inc., 199 F. Supp. 2d 362, 381 (M.D.N.C. 2002), aff'd sub nom., RJ Reynolds Tobacco Co. v. Philip Morris USA, Inc., 67 F. App'x 810 (4th Cir. 2003) (citing Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995); FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 460-61 (1986).

historical pricing data and Defendants' internal documents, models, and forecasts. Thus, common issues predominate as to market power.³⁹

3. Common Issues Predominate as to Antitrust Impact

To prove antitrust impact, a plaintiff must show some damage due to a defendant's antitrust violations. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114, n.9 (1969). At class certification, a plaintiff need only advance a plausible methodology to demonstrate that antitrust injury can be proven on a class-wide basis using common proof. *See Titanium Dioxide*, 284 F.R.D. at 345 (citing *Hydrogen Peroxide*, 552 F.3d at 311); *see also In re DRAM Antitrust Litig.*, No. 02-md-1486, 2006 WL 1530166, at *9 (N.D. Cal. June 5, 2006).



³⁹ See Flonase, 284 F.R.D. at 218 (predominance satisfied where relevant market and monopoly power would be proven through classwide, common evidence); *Teva Pharm. USA, Inc. v. Abbott Labs.*, 252 F.R.D. at 228 (common issues predominated as to defendant's monopoly power); *see also In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 663 (D. Conn. 2016) ("the relevant market in this [pay-for-delay] case is determined by the nature of the challenged agreement, [and] the only relevant market in this litigation is therefore the market of Aggrenox and its generic equivalents[.]").

⁴⁰ See Solodyn, 2017 WL 4621777, at *18 (concluding that End-Payors would "be able to show antitrust impact through common proof: if the jury finds Defendants' conduct violated the state laws in question here, the vast majority of [End-Payor plaintiffs] who purchased generic or brand Solodyn during this period [] experienced injury in the form of overcharges"); *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D. 551, 555-56 (S.D. Fla. 2001) ("No one contends that the defendants' comprehensive agreements made cheaper generic drugs available in the United States to some class members, but not others."); *see also Cardizem*, 200 F.R.D. at 308.

Any argument by Defendants that Plaintiffs do not demonstrate predominance due to the purported presence of uninjured class members should be rejected. Two federal courts citing First Circuit law recently rejected arguments that the presence of brand loyalists, coupons, vouchers and rebates caused non-common issues to predominate. *Loestrin*, 2019 WL 5406077, at *31-34; *Solodyn*, 2017 WL 4621777, at *15-18 (citing *Nexium*, 777 F.3d at 14). Where common liability questions predominate, courts generally find the predominance requirement met. *See Nexium*, 777 F.3d at 21 quoting *Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 108 (2d Cir. 2007); Buchman Decl., Ex. 22 (*Ryan-House*, No. 02-cv-442 (E.D. Va. July 28, 2004) (ECF No. 137), at 3 (finding that a pay-for-delay allegation "raises issues that predominate over any individual questions in this case, favoring class treatment.")); *see also* 2 William B. Rubenstein, *Newberg on Class Actions* § 4:54 (5th ed. 2012) ("the black letter rule is that individual damage calculations generally do not defeat a finding that common issues predominate"). Thus, proof of classwide impact is predominantly a common question.

4. Common Issues Predominate as to Measure of Damages

To meet the predominance requirement on measure of damages, "plaintiffs must show that damages can be reliably measured on a class-wide basis." *Celebrex*, 2017 WL 3669604, at *15) (citing *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013)). Damages in an antitrust case "may be determined on a classwide, or aggregate, basis . . . where the computerized records of the particular industry, supplemented by claims forms, provide a means to distribute damages to injured class members in the amount of their respective damages." In *re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 526 (S.D.N.Y. 1996); *accord, Lorazepam*, 202 F.R.D. at

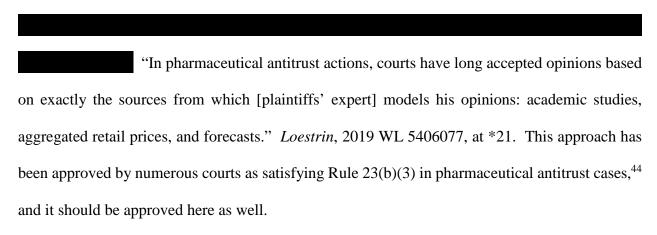
30.⁴¹ "[D]oubts as to the certainty of damages will be resolved against the wrongdoer, as the wrongdoer must bear the risks of the uncertainty which [its] conduct has created." *Sumitomo Copper*, 182 F.R.D. 85, 92-93 (S.D.N.Y. 1998) (quoting 22 Am. Jur. 2d *Damages* § 491 (1988)); *see Cardizem*, 200 F.R.D. at 350 (quoting 2 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 10.05 at 10-8 (3d ed. 1992); *In re Prudential Sales Practices*, 962 F. Supp. 450, 517 n.46 (D.N.J. 1997).

At the class certification stage, Plaintiffs are not required to "prove that every putative class member suffered injury." *Nexium*, 777 F.3d at 23. Moreover, certification is appropriate even if "damages will not be uniform across the class." *Id.* at 21.⁴² Damages calculations need not be exact, merely "consistent with the theory of liability." *Celebrex*, 2017 WL 3669604, at *16.⁴³ Where a plaintiff has presented a plausible methodology for calculating aggregate damages, class certification cannot be defeated merely by raising issues of fact with respect to the *amount* of damages. *Lidoderm*, 2017 WL 679367, at *11; *In re Pharm. Indust. Average Wholesale Price Litig.*, 582 F.3d at 197-98.

⁴¹ The fact of injury should not be confused with the amount of injury. *See Zenith Radio Corp.*, 395 U.S. at 114 n.9; *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 454-55 (3d Cir. 1977); *Cardizem*, 200 F.R.D. at 307.

⁴² See also Lidoderm, 2017 WL 679367, at *11 ("[D]ifferences in damages will rarely suffice to defeat class certification."); *Flonase*, 284 F.R.D. at 232 (individual issues concerning allocation of damages among class members do not defeat class certification).

⁴³ See also Nexium, 777 F.3d at 19; Solodyn, 2017 WL 4621777, at *19; In re Dial Complete Mktg. & Sales Practices Litig., 320 F.R.D. 326, 337 (D.N.H. 2017), (recognizing that "at the class certification stage, it is not necessary that class damages be calculated to a mathematical certainty.").



There is no risk that the aggregate damages model will fail to "reflect the liability theory," because Plaintiffs' damages theory is the same for all claims: Plaintiffs and members of the Class were overcharged for purchases of Zetia and its generic alternative as a result of Defendants' anticompetitive conduct.⁴⁵ Moreover, the Class exclusions have been crafted to provide objective criteria that can be used to ensure that Class recoveries are restricted to TPPs who suffered overcharge damages.

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⁴⁴ See, e.g., Nexium, 297 F.R.D. at 176-183 (transactional data and expert's damages model); Lidoderm, 2017 WL 679367, at *17 ("defendants' own forecasts, academic research applicable to the generic/brand drug pricing market, and [their expert's] model"); Teva Pharm., 252 F.R.D. at 229-30 ("scholarly economic literature, governmental studies and empirical evidence analyzing the market wide effects of unfettered generic competition on the prices and market shares of both brand and generic drugs"); Cardizem, 200 F.R.D. at 340-42 (economic literature, projections and sales data); Flonase, 284 F.R.D. at 220-225 (market data and general economic principles). See also Relafen, 221 F.R.D. at 275, Terazosin, 220 F.R.D. at 698-99; In re Cipro Cases I & II, 17 Cal. Rptr. 3d 1, 6 (Cal. App. Ct. 2004).

⁴⁵ Nexium, 777 F.3d at 23 (citing Comcast Corp. v. Behrend, 133 S. Ct. 1426 (2013)); Lidoderm, 2017 WL 679367, at *24 (rejecting challenge to end-payor's damages calculation under Comcast because plaintiffs "have one theory of injury and one consistent theory of damages").

Rprt. ¶¶ 37-63. To the extent Defendants attempt to speculate about small numbers of members of the Class who purportedly may not have been injured, "'[e]xcluding all uninjured class members at the certification stage is almost impossible in many cases[.]" *Krakauer*, 311 F.R.D. at 396 (quoting *Nexium*, 777 F.3d at 22). Although a class may not be "certified if it is apparent that it contains a great many persons who have suffered no injury at the hands of the defendant . . . [t]here is no precise measure of 'a great many.' Such determinations are a matter of degree and will turn on the facts as they appear from case to case." *Id.* (internal citations and quotation marks omitted).⁴⁶ Thus, common issues predominate as to the *quantum* of damages.

B. A Class Action Is Superior for Litigating this Dispute and Is Manageable

Rule 23(b)(3)'s superiority requirement is also satisfied here. The superiority requirement seeks to ensure that a class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable consequences." *Amchem*, 521 U.S. at 615; *Celebrex*, 2017 WL 3669604, at *17 (quoting *Amchem*, 521 U.S. at 615). "In deciding whether certification of a class is superior to other trial methods, courts consider whether the resolution of common issues advances the litigation as a whole, as opposed to leaving a large number of issues for case-by-case adjudication." *Titanium Dioxide*, 284 F.R.D. at 349 (quoting *In re Polyester Staple*

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⁴⁶ See also Solodyn, 2017 WL 4621777, at *10 (quoting Nexium, 777 F.3d at 25) ("[a] class may be certified even if it contains 'a de minimis number of potentially uninjured parties[.]'"); accord Lidoderm, 2017 WL 679367, at *11, 20; Flonase, 284 F.R.D. at 226-27. In Solodyn, 2017 WL 4621777, at *18, the court rejected Defendants' argument that there were many uninjured TPP class members who insured brand-loyal consumers or only covered generic Solodyn, noting the great "likelihood that Defendants' arguments are inflating the number of uninjured members" because "[t]hird party payors, like all antitrust plaintiffs "need only suffer damage on one purchase to be injured . . . an insurer with brand-loyal members is only uninjured here if every one of its members would have been brand-loyal for all Solodyn purchases in each 'but-for' scenario[,]" which was "highly unlikely); see also Loestrin, 2019 WL 5406077, at *31 (End-Payor plaintiffs demonstrated that TPPs were "injured because they would have made at least a single purchase of an AB-rated generic equivalent in the but-for world.").

Antitrust Litig., No. 03-cv-1516, 2007 WL 2111380, at *31 (W.D.N.C. July 19, 2007). "The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." *Amchem*, 521 U.S. at 617 (quoting *Mace v. Van Ru Credit Corp.*, 109 F.3d 338, 344 (7th Cir. 1997) (internal quotation marks omitted).⁴⁷

This is a classic case in which a class action is superior to the alternative: thousands of individual actions. Liability focuses on Defendants' anticompetitive conduct concerning Zetia. The misconduct resulted in higher prices which impacted class members in a uniform way. Damages in this case are susceptible to statistical proof in the same manner approved and followed in countless previous antitrust cases.⁴⁸ In addition, the large size of the Class makes a class action the superior method for the fair and efficient adjudication of the controversy. *NASDAQ*, 169 F.R.D. at 528-29 (certifying class involving millions of transactions and finding that "the size of the class militates in favor of, not against[,] certification" because "[d]efendants should not be permitted to avoid responsibility for the magnitude of their alleged conspiracy."). Accordingly, the Class should be certified.

Finally, Plaintiffs are not aware of any management difficulties that will be encountered in the litigation on behalf of the Class.⁴⁹ The manageability factor focuses on "the practical problems that may render the class action format inappropriate for a particular suit." *Eisen v. Carlisle & Jacqueline*, 417 U.S. 156, 164 (1974). Denial of class certification on the grounds of "vaguely perceived manageability problems" is disfavored because such a result is counter to the policy

 $^{^{47}}$ See also Solodyn, 2017 WL 4621777, at *21; Kinney v. Metro Glob. Media, Inc., No. 99-cv-579, 2002 WL 31015604, at *6 (D.R.I. Aug. 22, 2002).

⁴⁸ See, e.g., Loestrin, 2019 WL 5406077, at *35, Suboxone, 2019 WL 4735520, at *34; Solodyn, 2017 WL 4621777, at *19.

⁴⁹ Plaintiffs submit a Proposed Trial Management Plan as Buchman Decl., Ex. 21.

behind Rule 23." *Yaffe v. Powers*, 454 F.2d 1362, 1365 (1st Cir. 1972). Moreover, manageability is rarely an impediment to class certification in cases like this one, where "the fact of injury and damage breaks down in what may be characterized as 'virtually a mechanical task,' 'capable of mathematical or formula calculation." *Pitt v. City of Portsmouth*, 221 F.R.D. 438, 447 (E.D. Va. 2004) (quoting *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 67 (4th Cir. 1977)).

Prosecution of these claims in a class action will undoubtedly "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated." *Celebrex*, 2017 WL 3669604, at *17 (quoting *Amchem*, 521 U.S. at 615); *see also Relafen*, 221 F.R.D. at 287-88; *Flonase*, 284 F.R.D. at 234. Indeed, Defendants acknowledged the benefits of consolidating these actions before the Judicial Panel on Multi-District Litigation, including conservation of the resources of the parties and the courts and avoidance of inconsistent rulings. ⁵⁰

V. PLAINTIFFS AND ABSENT CLASS MEMBERS HAVE ARTICLE III STANDING

The Court previously deferred the issue of Article III standing in states other than those in which the named Plaintiffs made purchases until its decision on class certification. *In re Zetia* (*Ezetimibe*) *Antitrust Litig.*, No. 18-md-2836, 2019 WL 3761680, at *10 (E.D. Va. Aug. 9, 2019). Because, as shown above, certification of the Class with the named Plaintiffs as Class representatives is appropriate, the Class representatives may properly represent absent Class members on those Class members' claims in all other indirect purchaser states:

[W]hether named plaintiffs may properly represent absent class members is exactly the focus of the Rule 23 class certification analysis. The named class representatives are not themselves seeking recovery under the laws of foreign states. They merely allege that all the claims derive from the same source – Defendants' unlawful reverse payment Settlement Agreement. And the proposed class members from those foreign states would, if certified, undoubtedly have standing to pursue claims under those states' laws.

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⁵⁰ Response of Glenmark Defendants to Motion for Consolidation at 5, *In re Zetia (Ezetimibe) Antitrust Litig.*, MDL No. 2836 (J.P.M.L. Mar. 2, 2018) (ECF No. 23).

Zetia, 2019 WL 1397228, at *22-23; see Zetia, 2019 WL 3761680, at *10 (adopting "analysis and

conclusion"). Accordingly, named Plaintiffs and the absent Class members possess Article III

standing to assert claims under the laws of the states where they purchased, paid and/or provided

reimbursement for Zetia or generic Zetia, and the named Plaintiffs may represent all of those

claims under Rule 23.

COUNSEL MEET THE REQUIREMENTS OF RULE 23(G) VI.

The Court previously appointed Motley Rice LLC and Miller Law LLC as Interim Co-

Lead Counsel after reviewing their credentials and entertaining argument. The Court also

appointed Furniss, Davis, Rashkind and Saunders as Liaison Counsel. Both Interim Co-Lead and

Liaison Counsel have fulfilled their obligations and commitments required under Rule 23(g)

diligently and faithfully, and are committed to continuing to do so. Over the past nearly two

decades, courts, including this Court, have recognized that Interim Co-Lead Counsel possess the

experience and skills necessary to bring this type of case to a successful conclusion and appointed

them as Co-Lead counsel in similar pharmaceutical antitrust litigation.⁵¹ Counsel satisfy the

requirements of Rule 23(g) and, therefore, respectfully request to be appointed as Class Counsel

and Liaison Counsel.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this motion be granted in its

entirety.

Dated: November 18, 2019

Respectfully submitted,

By: /s/ James A. Cales III

⁵¹ See, e.g., In re Loestrin 24 FE Antitrust Litig., No. 13-md-2472 (D.R.I Sept. 17, 2019) (ECF No. 1226) (Class Certification Order) at 3; In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-md-2445 (E.D. Pa. Sept. 27, 2019) (ECF No. 588) (Class

Certification Order) at 3.

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CERTIFICATE OF SERVICE

I hereby certify that on November 18, 2019, a true copy of the foregoing document was

served on all counsel of record by electronically filing the document with the Court's CM/ECF

system.

/s/ James A. Cales III

James A. Cales III